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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/768,348	01/30/2004	Ramachandran Thembalath	124907-00107	6363

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EXAMINER	
TRAN, SUSAN T	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/768,348	THEMBALATH ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-51* is/are pending in the application.

4a) Of the above claim(s) *41,42 and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-40,43-49 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/01/06 has been entered.

Election/Restrictions

Newly submitted claims 41, 42 and 50 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the original claims are drawn to capsule which is classified in 424/451. Newly filed claims are drawn to tablet which is classified in 424, subclass 464. Because these inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 41, 42 and 50 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29, 34, 36, 45 and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. While application's specification discloses a ratio between polysorbate 80 and ethylcellulose is 1.00:0.165 (example 1). It appears that applicant's specification does not provide support for the ratio of 1.00:*1.65*. In accordance with MPEP§714.02, applicant should specifically point out support for any amendments made to the disclosure.

Regarding claims 29 and 45, while applicant's specification disclosed the coated core is mixed with excipients, and then compressed into tablet (outer layer) or incorporated into capsule shells (outer layer) (example 1). The specification, however, does not provide support for capsule as an outer layer that further comprises one or more excipients as recited in claims 29 and 45.

Claims 28-40, 43-49 and 51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for manufacturing an active core coated with a coating solution, does not reasonably provide enablement for a normal release coating (non-controlled release). The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." In *In re Wands*, these factors include:

1) The nature of the invention;

2) The state of the prior art;

3) The level of one of ordinary skill;

4) The level of predictability in the art;

5) The breadth of the claims;

6) The amount of direction or guidance provided by the inventor;

7) The existence of working examples; and

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation. These factors are discussed in detailed as follow:

1) The nature of the invention: the invention is directed to a process for manufacturing a pharmaceutical drug product having an active core being coated with a coating solution comprising mixture of ethylcellulose, organic solvent, and surfactant.

2) The state of the prior art: the state of the art is high.

3) The level of one of ordinary skill: the ordinary skill in the art is high (PhD level technology).

4) The level of predictability in the art: there is no predictability in the art of the coating solution that is adapted to allow normal release of the active in the core. This is because it is well known in pharmaceutical art that ethylcellulose is often used as a coating polymer to provide controlled release of active agent. See for example, the teaching in Dahlinder et al. US 4,927,640 at column 3, lines 20-27.

5) The breadth of the claims: instant independent claims are broad in term of using ethylcellulose in a coating solution.

6) The amount of direction or guidance provided by the inventor: applicant's specification discloses examples of different preparations, however, the specification fails to disclose data showing the release rate that is not controlled release. Contrary to the claims, applicant's specification discloses a film coating made of hydrophobic coating materials such as hydroxypropyl methyl cellulose (HPMC) to help retard against degradation. One of the causes for degradation is the acid pH in the stomach. Thus, many acid labile drugs are coated with hydrophobic materials to control the release of the drug in the GI tract. This fact is evident by the teachings of Dahlinder et al. US 4,927,640 at column 3, lines 10-18).

7) The existence of working examples: instant specification shows three examples, however, no release rate was disclosed.

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: it would require an undue experimentation by one of ordinary skill in the art to make and use the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 28-40, 43-49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buxton et al. US 5,601,845, in view of Patel et al. US 6,248,363 and Chen et al. US 6,270,805.

Buxton teaches a coating composition comprising ethyl cellulose, polysorbate 80 as a surfactant, plasticizer, and mixture of solvent selected from dichloromethane, ethanol, methanol, acetone, and isopropyl alcohol (see abstract, column 2, lines 31-67, and column 3, lines 3-9). Buxton also teaches the process comprising mixing the

ingredients of the coating composition, applying the coating to a drug spheroid core, the coated spheroid is filled into gelatin capsule (column 4, lines 1-25).

Buxton does not expressly the "normal release" release dosage form. However, absent of evidence to the contrary, applicant is invited to provide data showing that the formulation taught by Buxton does not have similar release rate as the claimed formulation. This is because Buxton teaches the use of similar ingredients for the same purpose, namely, using ethylcellulose, polysorbate 80, and organic solvent to obtain a coating solution.

However, to be more specific, Patel is cited in combination with Buxton. Patel teaches an oral dosage form comprising paroxetine and salts thereof (column 6, lines 60; and claim 12). The dosage form is coated with ethyl cellulose for a variety of reasons (column 42, lines 22-28). Thus, it would have been obvious to one of ordinary skill in the art to modify the coating of Buxton using the seal coat in view of the teaching of Patel to obtain the claimed invention, because Buxton teaches the use of ethyl cellulose as a suitable coating polymer, and because Patel teaching a seal coating using the claimed polymer for a variety of reasons, *e.g.*, particle porosity reduction, reduce dust, chemical protection, mask taste, reduce odor, and the like (column 42, lines 22-28).

In the case that applicant argues that Patel teaches paroxetine hydrochloride in a long list.

Chen teaches a controlled release formulation for water-soluble drugs include diltiazem, and paroxetine hydrochloride (column 3, lines 3-10). Thus, it would have

been obvious for one of ordinary skill in the art to modify the spheroid formulation of Buxton using paroxetine in view of the teaching of Chen, because Chen teaches the similarity of water-soluble drugs including diltiazem and paroxetine (column 3, lines 3-9), and because Buxton teaches a controlled release formulation for diltiazem.

The cited references do not teach the claimed ratio between polysorbate 80 and ethyl cellulose. However, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation determine suitable amounts of polysorbate 80 and ethyl cellulose to obtain the claimed invention, because Buxton teaches the use of ethyl cellulose as a suitable coating polymer and polysorbate 80 as a suitable surfactant in a controlled release formulation, and because Chen teaches the use of ethyl cellulose as a coating polymer useful to control the release rate of water-soluble drug.

Response to Arguments

Applicant's arguments filed 12/01/06 have been fully considered but they are not persuasive.

Applicant argues that neither Buxton nor Chen teach a "normal release" drug substance coating or drug formulation.

However, the present specification does not define the term "normal release" in such a way that it precludes "controlled release", "sustained release", "modified release", and the like. Stedman's Medical Dictionary defines the term "normal" as typical and usual. "Controlled release" taught in Buxton is very typical (normal) in pharmaceutical art. Besides, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Buxton is cited in view of Patel. Patel is cited for the teaching of multiple functions coating composition comprises ethylcellulose. Chen is cited solely for the teaching of the desirability of coating the claimed active agent is well known in the art.

Applicant argues that Patel does not teach using ethylcellulose for inhibiting moisture degradation while providing for "normal release" of an active ingredient.

However, it is not necessary for the prior art to show each and every property of the claimed product (see *In re Best*, Bolton and Shaw (CCPA) 195 USPQ 430, 10/13/1977). The claiming of a new use, new function or unknown property which is inherently present in the prior art does not make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). It is the position of the examiner that the use of the same coating polymeric (ethylcellulose) would necessitate at least similar properties, such as "normal release" or "inhibiting moisture degradation". It is noted that products of identical chemical composition cannot have mutually exclusive

properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

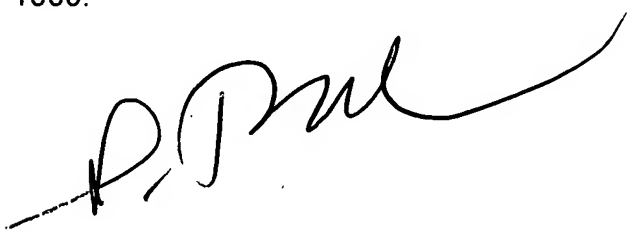
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



S. Tran
Examiner
Art Unit 1615